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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,468	06/14/2006	Myriam Richelle	3712036.00737	6965
29157 7590 02/24/2010 K&L. Gates LLP P.O. Box 1135			EXAMINER	
			CHEN, CATHERYNE	
CHICAGO, IL	. 60690		ART UNIT	PAPER NUMBER
			1655	•
			NOTIFICATION DATE	DELIVERY MODE
			02/24/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

## Application No. Applicant(s) 10/596,468 RICHELLE ET AL. Office Action Summary Examiner Art Unit CATHERYNE CHEN 1655 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 07 December 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-9,11-14,16,19,20,23,24 and 27 is/are pending in the application. 4a) Of the above claim(s) 1-8.19 and 20 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 9, 11-14, 16, 23, 24, 27 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of informal Patent Application

#### DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Dec. 7, 2009 has been entered.

Claims 9, 11-14, 16, 23-24, and 27 have been examined on the merits (claims 1-8, 19, and 20 remain withdrawn from consideration).

## Claim Objections

Claim 9 is objected to because of the following informalities: There is an extra word "the" after the phrase "improvement in." Appropriate correction is required.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 9, 11-14, 16, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In Claim 9, the term "elderly" is not found in the Specification. This limitation is deemed new matter and should be deleted from the claim or, alternatively, Applicant should particular point to adequate support for this limitation in the instant specification.

Appropriate correction is required.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 12, 14, 16, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Olguin (US 6159475).

Olguin teaches a hair growth formulation for scalp stimulation for people with receding hairlines from age 16-94 (the latter of which are elderly people) with hesperidins (column 1, lines 7-8, 42; column 2, lines 1-3, 28). Scalp is skin on the head. Lemon extract is made from lemon peel and includes bioflavonoids (Abstract). Bioflavonoids contain hesperdins (Table 1). Lemon is a citrus fruit.

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Claims 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bidel (US 5849786).

Bidel teaches hesperidin orally absorbed by subject at first sign of herpes outbreak (Example 2). Herepes simplex virus attack the skin (column 1, lines 15-17). A method for treating herpes administered to a patient in need thereof (Claim1), administered orally (Claim 2).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11-14, 16, 23-24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olguin (US 6159475) in view of Cho et al. (EP 0774749 A2).

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Olguin teaches a hair growth formulation for scalp stimulation for people with receding hairlines from age 16-94 (the latter of which are elderly people) with 154 mg of hesperidins (column 1, lines 7-8, 42; column 2, lines 1-3, 28). Scalp is skin on the head. Lemon extract is made from lemon peel and includes bioflavonoids (Abstract). Bioflavonoids contain hesperdins (Table 1). Lemon is a citrus fruit.

However, Olguin does not teach from 0.01 mg to 1 g of aglycone hesperidin, improve cytoprotection of the skin or to reduce inflammation of the skin.

Cho et al. teaches cosmetic compositions containing hesperetin to enhance kerationocyte differentiation in skin, thus decreasing skin dryness and decreasing appearance of wrinkles (Abstract), in cosmetically acceptable vehicle for the flavanones (page 3, line 13). The invention encompasses a cosmetic method for treating the appearance of wrinkled, flaky, aged or photodamaged skin (page 2, lines 32-33) for human skin (page 8, line 55). Hesperetin is the aglycone equivalent of hesperidin (see Description, paragraph 3, Hesperidin170 (http://170.107.206.70/drug\_info/nmdrugprofiles/nutsupdrugs/hes\_0295.shtml). Hesperetin from 0.001-5% weight can be translated to encompass 0.001-5 g.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hesperetin on aging elderly because Cho et al. teaches hesperetin to enhance kerationocyte differentiation in skin, thus decreasing skin dryness and decreasing appearance of wrinkles (Abstract) for treating the appearance of wrinkled, flaky, aged or photodamaged skin (page 2, lines 32-33). One would have

Treatment of photodamaged skin would confer cytoprotection of skin.

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been motivated to make hesperetin for aging elderly for the expected benefit of scalp stimulating for the elderly as taught by Olguin and reducing wrinkles in aged skin as taught by Cho et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising from 0.01 mg to 1 g of hesperetin for the following reasons. The references do teach the composition for treating skin. Cho et al. teaches hesperetin from 0.001-5% weight, which can be translated to encompass 0.001-5 g. Thus, the range from 0.01 mg to 1 g is encompassed by the teachings of the reference, and would have been obvious to use. Thus, it would have been obvious to make a concentrated composition containing hesperetin for use as a pharmaceutical agent. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the

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reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen Patent Examiner, Art Unit 1655 /Christopher R. Tate/ Primary Examiner, Art Unit 1655